



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/165,546      | 10/02/1998  | KNUTH ALEXANDER      | LUD5466.4-JE        | 8012             |

24972 7590 03/14/2002

FULBRIGHT & JAWORSKI, LLP  
666 FIFTH AVE  
NEW YORK, NY 10103-3198

EXAMINER

DECLoux, AMY M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

DATE MAILED: 03/14/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/165,546

Applicant(s)

Alexander et al.

Examiner

DeCloux, Amy

Art Unit

1644

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Dec 14, 2001

2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 6-8, 11-13, 16-54, 61-81, and 84-88 is/are pending in the application.

4a) Of the above, claim(s) 6-8, 11-13, 16-54, and 61-73 is/are withdrawn from consideration.

5) ☒ Claim(s) 84 and 88 is/are allowed.

6) ☒ Claim(s) 74, 75, 78, 85, and 87 is/are rejected.

7) ☒ Claim(s) 76, 77, 79-81, and 86 is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's amendments, filed 12-14-2001 (Papers<sup>25</sup> and 26) are acknowledged and have been entered. Claims 6-8, 11-13, 16-54 and 61-81 and 84-88 are pending. Claims 6-8, 11-13, 16-54, and 61-73 are withdrawn from consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. Claims 74-81 and 84-87 are under consideration currently.

2. The rejections of record can be found in the previous Office Action, mailed 10-16-01 (Paper No. 21). In view of applicant's amendment, filed 12-14-2001, the outstanding 112 second rejections have been withdrawn. However, the 112 first paragraph rejection has been maintained. Also, in view of Applicant's amended claims, new grounds of rejection have been applied to the instant claims.

3. The oath or declaration stands defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

In Applicant's amendment, faxed 8-6-2001, Applicant states that this will be dealt with in the future.

4. In the remarks section of the amendment, filed 12-14-2001, Applicants cite U.S. Patent 6,251,603 to show that ESO is known to be processed in vivo into peptides which complex with Class II molecules, with which the examiner agrees. However, the relevance of how said citation pertains to which rejection, is not clear.

5. **MAINTAINED** claims 74-75, 78 and 82 **and applied to newly added claim 85 and 87** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to the written description rejection, applicants point out that the motif they describe is essential to HLA-DR53 binding as established by Futaki et al (Immunogenetics 42:299-301 (1995)). However, the examiner notes that Futaki teaches on page 299, column 2, that said motif is for a peptide that binds a DR9 motif but not a DR53 motif. It is also noted that the instant claims recite DR53.

Also with regard to the written description rejection, applicants point out that Futaki et al describe peptides that range in length from 11 to 17 amino acids that do in fact bind HLA-DR53. However, the examiner notes that the recited peptides range from 18 to 25 amino acids and thus do not even overlap the size of peptides taught by Futaki

et al. Applicants also contend that the recited lengths of said peptides are not unreasonable in view of the showing of what is known in the art. However, applicant does not disclose art that shows peptides of the recited length with anchor residues at positions 1 and 4. Therefore, though there is a finite number of amino acids, as pointed out by the applicants, the written description requirement has not been satisfied because the disclosure fails to provide sufficient relevant identifying characteristics that identify members of the genus, and given the broad genus claimed, the disclosure of a few peptides of defined sequence is insufficient to describe the claimed genus.

Therefore, though applicant's arguments have been carefully considered, they are not deemed persuasive and the rejection is maintained and applied to newly added claims 85 and 87, which are substantially similar to now canceled claim 82.

#### NEW GROUNDS OF REJECTION

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 85 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 85 is not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation of a first isolated polypeptide, the amino acid sequence of which consists of the amino acid sequence set forth in SEQ ID NO:7 and at least one additional polypeptide of claim 74. There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter**. Applicant is invited to point out support for the instant claim.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

9. Claim 87 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 87 is indefinite in the recitation of "an amino acid sequence set forth in SEQ ID NO:1" since said SEQ ID NO:1 is a nucleic acid sequence.

10. Claim 84 is allowable because the prior art neither teaches nor suggests a composition comprising a first polypeptide consisting of amino acid sequence of SEQ ID NO:7, and at least one other polypeptide, the amino acid sequence of which is set forth at SEQ ID NO:4, 5 or 6.

Claim 88 is allowable because the prior art neither teaches nor suggests an isolated consisting of the amino acid sequence of SEQ ID NO:4.

11. Claims 76-77 and 79-81 and 86 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. Or a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner  
Group 1640

Serial No. 09/165,546  
Art Unit 1644

Technology Center 1600  
February 21, 2002

5

*David A. Saunders*

DAVID SAUNDERS  
PRIMARY EXAMINER

ART UNIT 182-104